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PBM and Pharmaceutical Company Mergers: Policy and Regulatory Implications

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A recent trend in the pharmaceutical industry has been for large pharmaceutical companies to acquire or merge with PBMs (prescriptionpharmacy-benefits-management companies).¹ Merck started this trend in November 1993 by merging with a PBM named Medco; two other pharmaceutical giants have followed suit. Since such mergers are a recent phenomenon, their full-scale implications are as yet unknown and there is little regulation in place specifically to address their potential effects. This essay describes the current state of affairs of PBM-pharmaceutical company alliances and explores their implications for the pharmaceutical and health care industries and the players involved. It further discusses the regulatory bodies involved, the measures they have taken to date, and possible future courses of action.

I. Describing the PBMs and the Mergers

A. The Structure and Function of PBMs

PBMs, or prescnptionpharmacy-benefits-management companies,² operate with the goal of bringing health care to new levels of efficiency in cost and quality through management of the phannaceutical end of the business.

PBMs continue to exist outside of mergers with pharmaceutical companies, but

¹•This essay will use the terms merger, acquisition, vertical-integration, alliance, and related terms interchangeably to refer to the phenomenon of large pharmaceutical companies buying PBMs.

² FDA has a different term for PB Ms. calling them instead PMCs, or pharmacy management companies.

the biggest and most powerful are those that have merged.³

Employers and managed-care organizations hire PBMs to administer the pharmaceutical portions of their health care plans. There are certain defining characteristics of PBMs. One central component is the maintenance of an information database, which usually tracks physicians' prescriptions, the drugs dispensed by pharmacists, and patterns of patient drug use for the patients who are covered under a plan the PBM is administering.⁴ The collected information in the database enables PBMs to do drug utilization review, which is an analysis of the data, revealing whether patients took their medications regularly and as prescribed, whether there were any adverse interactions between drugs, other relevant patient health history information, and information about doctors' patterns of prescribing.⁵ Such information could be invaluable to pharmaceutical companies in deciding how to label, market, and improve their products.

Another core characteristic of PBMs is their development and adherence to formularies (lists of drugs approved for use by those participating in the particular PBM's plan). PBMs decide which drugs to list on their formularies based on cost and effectiveness considerations. There is a trend toward including generics when feasible in order to save costs for plan sponsors.⁶ As this

³One source estimates that the three PBMs that have merged with pharmaceutical companies, (Medco, PCS, and Diversified), comprise 80% of the managed drug benefit market, while over 35 other companies share the rest of the market. *Doubts Emerge about Drug Industry Mergers; Acquisitions of Pharmacy Benefit Management Companies Raise Antitrust Concerns*, Business & Health, Nov., 1994, at 53 (hereinafter *Doubts Emerge*).

⁴Nancy A. Nichols, *Medicine, Management, and Mergers: An Interview with Merck's P. Roy Vagelos*, Harv. Bus. Rev., Nov.-Dec. 1994, at 105, 111; Anita M. McGahan, *Industry Structure and Competitive Advantage*, Harv. Bus. Rev., Nov.-Dec. 1994, at 115.

⁵McGahan, *sup-a* note 3, at 119-120.

⁶Nichols, *sup-a* note 3, at 110; McGahan, *sup-a* note 3, at 115, 119-120.

essay will discuss, the close ties between merged PBM and drug companies may affect the dynamic of the formulary, as the parent drug companies attempt to fill as much as possible of their PBMs' formularies with their own products.⁷ As part of the formulary system, PBMs pay pharmacists to call doctors who have prescribed a particular drug to ask them to switch the prescription to one that appears on the PBM's formulary, (which is usually a less-expensive alternative drug).⁸

One further defining aspect of PBMs is their emphasis on long-term health care, as exemplified by disease management (also called disease state management) programs. These programs currently target people with chronic diseases such as asthma and diabetes. Under such programs, pharmacists monitor patients' conditions, educate patients on proper medication usage, and advise them on measures for promoting their overall health (diet, exercise, etc.). The goal is to invest the resources early in caring for such patients in order to avoid the greater hospitalization costs that would accrue later if the disease were not properly treated.⁹ Recent innovations in long-term care include a capitation system, in which the plan sponsor pays a flat fee for a given period of time for drug coverage for all its constituents, rather than paying a per-drug charge. Capitation is basically an insurance-type of risk-sharing, which will require a lot of data from the PBMs in order to gauge properly. A similar flat-fee

⁷See, e.g., *Doubts Emerge*, *sup-a* note 2, at 53. One commentator affirmed, however, that no one drug manufacturer could supply the full range of drugs to fill a formulary, and that manufacturers need to get their products on more than one PBM's formula, even with an in-house PBM, in order to stay profitable. *id*

⁸McGahan, *sup-a* note 3, at 119-120.

⁹Nichols, *sup-a* note 3, at 112; Greg Muirhead, *The ABCs of PBMs; Pharmacy Benefit Managers Control*

system could be established for patients who have a particular disease and are participating in a disease management program as well.¹⁰

B. Vertically-Integrated Pharmaceutical Companies

Three of the largest pharmaceutical companies in the U.S. recently each have acquired a major PBM. Merck and Medco merged in November, 1993, starting the industry trend. Smithkline Beecham acquired Diversified Pharmaceutical Services in May 1994, followed by Eli Lilly's acquisition of PCS Health Systems in July 1994. These mergers provide key advantages to pharmaceutical companies: they provide an edge in the competitive drug industry, building in efficiencies that help the companies keep up with the demand for better health care at lower prices that characterizes the new managed care frontier.¹¹ As can be expected, the alliances provide drug companies with phenomenal access to data, as well as shift their focus to ways of promoting long-term health.¹² The mergers also provide important advantages to the PBMs involved. Merged PBMs have greater access to clinical resources, detail forces (salespersons who tell doctors about new drugs), research and development budgets, and disease management programs than do their

Pharmaceutical industry, Drug Topics, Sept. 5, 1994, at 76. For non-merged competitors.¹³ Vertically-organized pharmaceutical companies face special challenges, however, in that they simultaneously serve four different cus-

¹⁰McGahan, *supra* note 3, at 121.

¹¹Nichols, *supra* note 3, at 106.

¹²*Id.* at 106, 110.

¹³*Lilly's \$4 BIL Bid for PCS is Intermediate to Other Pharmaceutical Buyouts*, 43 F.D.C. REP. (The Green Sheet), July 18, 1994, at 2.

tomers: plan sponsors, pharmacists, physicians, and patients.¹⁴

II. Implications of the Mergers

A. How Mergers Affect the Various Players

1. Pharmacists

Pharmacists already were finding themselves at a crossroads in determining what their role should be in the medical community when PBMs added the job of requesting prescription-switches to the equation. Formerly seeing themselves as counselors, pharmacists in recent years have been finding their roles diminished even to the point of being mere drug dispensers. PBMs' offers of payment to pharmacists who would call doctors and request switches to formulary-listed drugs could be seen in one sense as a boon to the profession, giving pharmacists a newly-increased role in health care management (and associated cost-containment efforts). Payments for asking patients to switch also could be seen in this light, though perhaps less positively. There is also a more troubling side to such practices. PBMs that are allied with drug companies through mergers, or affiliated with them more loosely by contract, may not be promoting the drugs on their formularies solely for cost-effectiveness reasons, but also for the purpose of increasing the sales of their companies' products.¹⁵ Such a scenario is problematic for a number of reasons. Serious ethical problems arise when pharmacists, who have been regarded as unbiased and detached professionals, no matter what the details of their role, put themselves in the position of being deputies of the drug companies. An FDA Deputy Commissioner,

¹⁴Nichols, *sup-a* note 3, at 110.

¹⁵McGahan, *sup-a* note 3, at 115-116, 122-123; Gina Kolata, *Company News: Upjohn to Repay 8 States Over Drug Plan*, N.Y. Times, Aug. 2, 1994, at D1.

Maiy l*ndergast, criticized such practices in a September 1994 statement, challenging PBM formularies as tool(sj for marketing, calling pharmacists entities we thought were independent... [who] are really just agents of the drug companies and they are being paid to take the positions they take, and asserting that these [arrangements] undermine trust in the health care system.¹⁶

Another problem with the switching system is that doctors may not know that pharmacists are being paid to ask for the change in prescription.¹⁷ Such a situation carries over the ethical problems of pharmacists stepping out of their neutral roles and into those of secret partisans and, in addition, imports a risk in that doctors may think the pharmacist is calling because the substitute drug has been shown more effective, and as a result may not pay due attention to how safe or appropriate the substitution is for the particular patient or condition to be treated. The latter risk was part of what was at issue when a number of states investigated and fined the Upjohn company, (which is not merged with a PBM, incidentally), for paying pharmacists to encourage doctors and patients to switch from one of its diabetes drugs to another that was still under patent. The states charged that the company and the pharmacists failed to indicate that this switch put patients at risk because the two drugs were not wholly equivalent. Upjohn claimed that it was paying pharmacists for counseling patients and not for inducing them to switch.¹⁸

¹⁶*Drug Firms and 'ALUetP PEM Structures Being Perused by FDA, Promotional Materials Topic of Meetings with Merck, Lilly, Smithkline Beecham, and Pfizer*, 56 F-D-C REP. (The Pink Sheet), Oct. 17, 1994, at 8-9 [hereinafter *Drug Firms*].

¹⁷McCahan,sajp-a note 3, at 123.

¹⁸Id. at 123; Kolata, *sup-a* note 14, at D1; *Upjohn Violated State Business Practice Laws*, Marketletter, Aug. 8, 1994.

One way to remedy the problem of doctors (and patients) not knowing that pharmacists are being paid to recommend drug switches simply would be to require such disclosure on the part of the pharmacists. Advertisements and articles in medical journals also would get the word out. In addition, as a more complete and permanent fix, perhaps proof of actual counseling (which is what the drug companies and associated PBMs claim pharmacists are doing now) should be required. A counseling role, albeit funded by the drug companies and so not wholly neutral, would give back to pharmacists a more important role in health care. The counseling role for pharmacists that is envisioned and in place under disease management programs could serve as a model for the type of counseling pharmacists should perform.¹⁹ Pharmacists also have tossed their own solution into the mix by forming their own PBM, called PDN (Pharmacy Direct Network), which links community pharmacies and remains independent of drug companies and their PBMs, thereby avoiding the ethical problems associated with company payments for drug-switching.²⁰

2. Physicians

The biggest impact on doctors from the mergers probably will come from the information databases kept by the PBMs. Such databases have potential for both good and bad. On one hand, the increased information about how patients take their medications, the effects of the drugs, patient health his-

¹⁹Medco has instituted a two-phase Coordinated Care Network, which in its first phase gave pharmacists incentives for getting more formulary-listed drugs prescribed, and which in its second phase gave pharmacists additional compensation for counseling and monitoring patients. Perhaps a program like this is a good start in the direction of encouraging counseling by pharmacists. Muirhead, *sup-a* note 8, at 76.

²⁰Muirhead, *sup-a* note 8, at 76; Geoff Walden, *New Dynamics Emerge in Rx, Rx Mass Market Retail Pharmacy*, Chain Drug Rev., Aug. 29, 1994, at RX1.

tories, and adverse drug interactions could greatly improve doctors' prescribing approaches.²¹ At the same time, however, doctors may feel like Big Brother is watching. Since a doctor's prescribing habits are visible to anyone with access to the database, such publicity could affect autonomy, discretion, and perhaps even malpractice insurance. Further, PBMs can keep data, or even ratings, on how receptive a particular doctor is to requests to switch.²² Such ratings not only would be intrusive, but also may affect whether a particular doctor is approved and covered under a particular health plan. If such were the case, doctors would be forced to cave into requests to switch at the peril of losing patients who are enrolled in the particular plan.

Another troubling potentiality of the new merged PBMs is that they will offer incentives directly to doctors for prescribing drugs from their formularies. Putting aside for the moment the complicated issue of unapproved uses, hidden ties of doctors and drug companies have long been

an issue and might become more problematic in the face of vertical integration. Since doctors have been the traditional consumers to whom prescription drugs were marketed, drug companies have a history of furnishing doctors with gifts and other incentives, such as research grants, as a means of getting doctors to notice and prescribe their products.²³ PBMs with formulary lists may make the drug company connection seem less evident to doctors and

²¹ *Doubts Emerge*, *sup-a* note 2, at 53.

²² McGahan, *sup-a* note 3, at 120.

²³ The FDA can regulate the content of promotions, but, according to an FDA spokeswoman, Payment of a kickback for the prescribing of a particular product does not appear to be a violation of the FD&CJ Act. *Genemach Alleged Protropin Physician Inducement of Off-Label Use Under FDA Investigation; Agency Has Limited Authority over Foundations, Kickbacks*, 56 F-D-C REP. (The Pink Sheet), Aug. 22, 1994, at 3-5.

less to be guarded against. A doctor who lets her ethical guard down may end up settling for prescribing a particular drug when a different one may be more apt for a particular patient or condition. The patients would have no inkling of the doctor's hidden ties with the drug company and would simply have to trust that the prescription was appropriate.

3. Patients

The mergers may have positive and negative effects for the patients covered. On the positive side, patients may be getting improved health care in the sense that there would be increased education and supervision, perhaps more accurate prescribing, and an emphasis on preventive measures and disease management programs. Possible negatives include the loss of privacy associated with information databases, the possibility that the formulary they are under does not list the medicine that would best treat them, the lack of autonomy (and truly informed consent) that is associated with the hidden ties between drug companies, pharmacists, and doctors, and the lack of control in that plan sponsors and drug companies and their PBMs are determining what is best for the patients.

4. Plan Sponsors

In face of the mergers, plan sponsors will have to take extra care and stay well-informed to ensure that their PBMs are still loyal to them and are not just trying to promote sales of their parent drug companies' products. Plan sponsors could safeguard themselves by monitoring the value, quality, and effectiveness of the treatment their beneficiaries are receiving. Threats to switch

PBMs based on dissatisfaction with price, quality, or other factors may be effective, but become more problematic as most of the PBM power is concentrated in the three merged drug companies. Assurances by the merged PBMs that their formularies are not restricted to partisan products, but list the most cost-effective and quality drugs available may serve to ease the worries of plan sponsors.²⁴

5. Pharmaceutical Companies Not Merged With PBMs The PBM-drug company mergers may have any of a number of effects on non-vertically-integrated drug companies. The merged companies might hurt the non-merged competitively, forcing them to negotiate contracts of affiliation with non-merged PBMs.²⁵ Such contracts may become tougher to negotiate as more PBMs align themselves in one way or another with drug companies, so the non-merged drug companies should act quickly.²⁶ A greater concern, and one which worries the FDA, is that the non-merged companies will resort to questionable means of influencing prescribing and formularies as a way of gaining sales back from their merged competitors.²⁷ The FDA and other regulators will have to keep the entire pharmaceutical field in view when taking action to deal with the PBM-pharmaceutical company mergers.

B. Other Implications of the Mergers

1. Unapproved Uses of Approved Drugs

²⁴A Merck spokesman is cited as insisting that Medco will provide the least expensive and most appropriate medicine regardless of manufacturer. *Doubts Emerge*, *sup-a* note 2, at 53.

²⁵McGahan, *sup-a* note 3, at 120; Muirhead, *sup-a* note 8, at 76.

²⁶*Doubts Emerge*, *sup-a* note 2, at 53.

²⁷*Markettag Practices of Non-PBM Owning Companies Seeking Market Share Are An Agency Concern—FDA's Pendergast*, 56 F-D-C REP. (The Pink Sheet), Sept. 26, 1994, at 3 [hereinafter *Marketing Practices*].

The FDA prohibits drug manufacturers from promoting their drug products for unapproved uses. The situation becomes much less clear-cut in regard to PBMs merged with drug companies. The PBM may want to embrace the fact that doctors already are prescribing one of the company's products for an off-label use, or may want to encourage doctors to do so, but as the PBM is now part of the entire drug company, this may not be permissible. In some cases, it may be best for the patient if PBMs are allowed to encourage off-label use since that may be the most effective (and perhaps least expensive) drug on the market that can be used to treat the patient's condition. In other cases, there may be reasons for caution. First, the PBM could be promoting a drug for an off-label use not because it is more effective, but because it is made by its parent company. Second, with its data-collecting efforts, a PBM might try to run cheap, unofficial tests (on unsuspecting patients) by widely encouraging an unapproved use and then tracking the effects on patients. Such tests seem unethical, but, on the other hand, if they could be done with patients' informed consent they might be a way of collecting the data necessary for getting the drug approved for the new use. Whether merged PBMs are entitled to list unapproved uses on their formularies seems questionable. Even more dubious is the issue of whether these PBMs can pay pharmacists to encourage switches from approved drugs to unapproved uses of company or other formulary drugs.²⁸

The FDA is concerned about the possible ties between drug manufacturers, their acquired PBMs, and unapproved uses of the companies' prod-

²⁸ *Id*

ucts. Although the FDA is at an early stage in deciding how to regulate the mergers, it has addressed questions to the merged drug companies, some of which were specifically aimed at finding out what kind of materials might be used to promote off-label uses through PBMs.²⁹ FDA has shown a commitment to preventing advocacy of unapproved uses in drug company managed-care promotional materials, even without a drug company-PBM merger. FDA sent Lilly a warning letter over statements regarding unapproved uses that appeared in a managed care binder promoting its drug Axid. The promotional materials at issue dated from before Lilly had merged with PCS.³⁰ Even in the absence of FDA involvement, it seems likely that vertically-integrated drug companies would set up some of their own precautions for staying within the law, such as creating Chinese Walls between the drug manufacturing and PBM divisions of the company.

2. New Drug Research vs. Push for Generics

There are some indications that the mergers may deter new drug research. Merged drug manufacturers have new incentives to make generic drugs in a wide range of categories now that they each have a special relationship with a PBM and its formulary. If a company can fill a formulary with its own products, it can make money in a more certain way than through hit-or-miss new drug research. As a result, some of the funds that had been used to develop entirely new drugs may be diverted to the much simpler process of making me-

²⁹ *Drug Firms*, *sup-a* note 15, at 8-9.

³⁰ *Lilly Axid for GERD Promotions to Managed Care Cited in FDA Warning Letter; Cost-Effectiveness, Comparative Claims Also Deemed Misleading by the Agency*, 56 F-D-C REP. (The Pink Sheet), July 25, 1994, at 3-5 [hereinafter *Lilly AzzdJ*].

too drugs.³¹ Additional incentive for manufacturing generics comes from the fact that many patents will be expiring within the next five years, opening the field for me-too drugs.³² Some argue that the rise of PBMs has intensified price competition in the pharmaceutical industry, which will result in less profits and accordingly less money for research and development.³³ These fears all may prove unfounded, however, particularly in the cases of the vertically-integrated pharmaceutical companies. These companies are doing well in the competitive field, and have achieved much success and stature through their new drug discoveries. One new drug probably can do a lot more to send a company's stock prices soaring than a steady diet of generics. Further, these companies undoubtedly recognize the value of new drugs to society, so whether for altruistic reasons or more likely for public image reasons, the companies will continue to invest in new drugs.³⁴

3. Prescription vs. Over-the-Counter Status

The mergers may create incentives for keeping drugs under prescription, as opposed to available over-the-counter (OTC), in that there is an emphasis on information-collecting. Prescriptions serve the purpose of keeping these drugs and their use on the record, producing data desired by the PBMs and their parent pharmaceutical companies. Physicians and pharmacists probably also would favor keeping the status quo or converting even less drugs to

³¹Nichols, *supra* note 3, at 111.

³²McGahan, *supra* note 3, at 117.

³³kL at 116, 123.

³⁴Nichols, *supra* note 3, at 113. Merck's former CEO, P. Roy Vagelos predicted that Only a few pharmaceutical companies will survive the restructuring that has already begun, and the ones that do will have to excel at both research and the new distribution methods. *Id*

OTC purely for business reasons. Plan sponsors, on the other hand, might prefer if more drugs were changed to OTC since then they would not have to cover their costs. If plan sponsors fully bought into the long-term health care idea, however, they might not want such a change since patients may use medicine more appropriately if it is prescribed and supervised. Drug manufacturers may find themselves torn on this issue between the desire for record-keeping, and the wider distribution and greater sales that OTC status might provide.

III.Regulation and Regulatory Bodies

A.. Food & Drug Administration

The FDA is still in the early stages of deciding how to regulate vertically-integrated pharmaceutical companies.³⁵ It is gathering information by addressing questions to the merged companies themselves. Chief areas of concern seem to include independence between the drug companies and their acquired PBMs, whether the acquisitions were designed to help sell the manufacturers' products, formulary decision-making, incentives to switch products, product labeling and uses, unapproved uses, and data collection.³⁶ The FDA has authority over prescription drug manufacturers' promotional materials, and aims to ensure accuracy, reliability, and balance of information.³⁷ Judging from its activities prior to the mergers, the FDA seems likely to take action in this sphere. For example, the FDA had sent a warning letter to Upjohn regarding the marketing of its diabetes drugs, (discussed above in section II.A.1), in which

³⁵ *Marketing Practices*, *sup-a* note 26, at 3; *Drug Firms*, *sup-a* note 15, at 8-9.

³⁶ *Drug Firms*, *sup-a* note 15, at 8-9.

³⁷ *Id* See also Peter Barton Hutt & Richard A. Merrill, Food and Drug **Law** 454, 459, 464 (2d. ed.

it also mentioned the switching incentive program.³⁸ FDA also issued a warning letter involving Lilly's managed-care promotional materials which included unapproved uses of its drug Axid (as discussed above in section [I.B. 1]).³⁹ If these prior activities are any indication, the drug-switching incentive programs and the problem of unapproved uses encouraged by merged PBMs may be some of the first effects of the merger that FDA will target.

B. Federal Trade Commission

The FDA is not the only agency with jurisdiction over the implications of pharmaceutical company-PBM mergers. The FTC approves such mergers and keeps a watchful eye out for antitrust problems and drug pricing. While the FTC approved the Merck and Smithkline Beecham PBM acquisitions without limitations, it has since imposed limits on Lilly's acquisition of PCS and has now announced that it will go back and examine the other two companies' mergers. The FTC's concerns relating to Lilly were in ensuring that PCS carries drugs made by Lilly's competitors, (in order to avoid driving out competition, raising prices, and reducing quality and variety), and that Lilly not use its new PBM to gain information about competitors' drugs. The measures the FTC imposed include a requirement of an open formulary, approved by an

1991) independent committee, the creation of a fire wall between the drug manufacturing and PBM businesses (to keep competitors' confidential information, such as pricing, out of Lilly's view), and a requirement of FTC clearance for future PBM acquisitions.⁴⁰

³⁸Kolata, *sup-a* note 14, at D1.

³⁹*Lilly Axid*, *sup-a* note 29, at 3-5.

⁴⁰Anne E. Tergesen, *Merck Put on Merger Hot Seat*, *Bergen Record*, Nov. 8, 1994,

C. Other Government Involvement

Members of Congress have carved out a role for themselves on the issue of vertically-integrated pharmaceutical companies. Senators Howard Metzenbaum and David Pryor wrote to the FTC regarding the Lilly-PCS merger asking for close scrutiny based on its potential implications for price competition.⁴¹ Representative Ron Wyden (and his Committee on Small Business) requested a General Accounting Office study of the mergers.⁴² State governments have also gotten into the act. New York State, for example, through its Attorney General investigated Upjohn's diabetes drug marketing and drug-switching incentive program. The New York Attorney General also initiated legislation making it illegal for companies to pay pharmacists to induce drug switches.⁴³ One can expect more such activity on all fronts as the pharmaceutical market further solidifies.

IV. Conclusion

Mergers between large pharmaceutical companies and PBMs have had and will have far-reaching implications that affect all the players in the managed health care field, and the pharmaceutical and health care industries in general. While regulation thus far has been only preliminary, the full-scale regulation that can be expected from several sources probably will serve to check many of these effects. In the end, regulation may cut into many of the

at COL; *Smithkline Beecham Diversified Takeover Under FTC Eye*, Marketletter, Nov. 21, 1994.

⁴¹ *Lawmakers Eyeing Drug Networks*, **Health Legislation & Regulation**, Nov. 2, 1994; Terjesen, *sup-a* note 39, at COL.

⁴² *Eyeing Drug Networks*, *sup-a* **note 40**; Muirhead, *sup-a* **note 8**, at 76.

⁴³ *Upjohn Violated State Business Practice Laws*, *sup-a* **note 17**; Kolata, *sup-a* note 14, at DL.

competitive advantages the drug companies had hoped to garner in entering into such mergers.